

Memorandum

Subject

Internet Presentation with AmerisourceBergen on August 10, 2005
(DFN: 060-06.05)

Date

August 16, 2005

To

William J. Walker
Deputy Assistant Administrator
Office of Diversion Control

From


Michael R. Mapes, Chief
E-Commerce Section (ODC)

On August 10, 2005, a meeting was held at the Office of Diversion Control conference room. In attendance were Steve Mays, Director of Regulatory Affairs for AmerisourceBergen, Michael R. Mapes, Chief, E-Commerce Section, [REDACTED] Office of Chief Counsel, Diversion & Regulatory Litigation Division, and Kyle J. Wright, Chief, E-Commerce Operations Unit. The purpose of the meeting was to address the illegal domestic Internet pharmacy problem and their source of supply.

Mr. Mapes opened the meeting by presenting to Mr. Mays a power point briefing which explained the common characteristics of Internet pharmacies and why their activities are illegal. Reviewed with Mr. Mays were:

- Supreme Court Cases and Immediate Suspension orders of Internet pharmacies.
- Establishing the medical need necessity for a prescription to be legal.
- The DEA Internet Policy.
- Verified Internet Pharmacy Practice Sites (VIPPS).
- Policies published by the American Medical Association (AMA) and the Federation of State Medical Boards.
- Review of the suspicious order requirements Title 21, Code of Federal Regulations.
- Common practices and ordering patterns of Internet pharmacies.
- Examples of two Internet pharmacies highlighting the brazenness of activity to which Internet pharmacies will go to.

After the presentation, Mr. Mays informed representatives of the DEA that AmerisourceBergen does not want to be associated with this type of illegal activity and reviews its customers thoroughly before engaging in businesses with them. At this time, Mr. Mays presented a sales profile for [REDACTED], a pharmacy in Colorado, which is allegedly conducting Internet sales. Mr. Mays informed the representatives of the DEA that the purchases by this pharmacy were somewhat suspicious but the pharmacy had also ordered and continues to order non-controlled substances commensurate with their purchases of controlled substances. The pharmacy's controlled substance purchases were primarily hydrocodone and Norco.

PLAINTIFFS TRIAL
EXHIBIT
P-09112_00001

Mr. Mapes, [REDACTED] and Mr. Wright all in turn expressed to Mr. Mays, the extent to which an Internet pharmacy will go to appear as legitimate as possible to include: leasing office space, purchasing appropriate amounts of other products, using multiple DEA registrations in order to stay under excessive purchasing reporting, etc., to give the guise of being a regular pharmacy. Yet, if the account managers for AmerisourceBergen were to scratch the surface a little deeper, they would readily see the real operations of such pharmacies.

Mr. Mays stated that upon return to his office, sales to [REDACTED] would be reviewed and AmerisourceBergen would begin a top to bottom review of the company's policies and sales practices. Mr. Mays further expressed that AmerisourceBergen was willing to do all that it could to help avert this serious issue of Internet pharmacies.

In consultation with [REDACTED] it was agreed, that if E-Commerce Operations (ODCO) were to identify a highly suspicious pharmacy to which AmerisourceBergen was the wholesaler, ODCO would notify AmerisourceBergen via e-mail of the suspicious activity for AmerisourceBergen to review and take the actions the company deems appropriate. Mr. Mapes also informed Mr. Mays, if he desired further information, or training, to notify ODCO which would provide the requested information or training.

The meeting between AmerisourceBergen and DEA was ended at this time, with each party having a clearer understanding and agreement as to how best address the sources of supply to Internet pharmacies.

Attachments:

1. Briefing Binder
2. [REDACTED] printout

INTERNET PHARMACY DATA

Meeting With
AmerisourceBergen
DEA Headquarters
August 10, 2005

Internet Pharmacies

- Domestic Based
 - Related to an existing pharmacy
 - Walk in patients with prescriptions
 - Some legitimate some not
 - Unrelated to brick and mortar pharmacy
 - No local patients or doctors
 - No walk-in business
- Foreign based

ISSUES TO CONSIDER

- Frequency of Orders
- Size of Orders
- Range of Products Purchased
- Payment Method
- Pharmacy Location
- % Controlled vs. % Non-Controlled
- Customer pick up at distributor

DEA DISTRIBUTOR REGISTRATIONS

- Title 21 United States Code, Section 823
 - Is the registration in the public interest?
 - Maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical channels

Supreme Court Case

- Direct Sales Co, Inc. v. United States (1943)
 - Mail order sales to doctor
 - Most sales were Morphine
 - Increase in quantities purchased
 - Business practices attracted customers who were violating the law
 - Drugs have inherent susceptibility to harmful and illegal use

EZ RX, LLC

- 69 FR 63,178 (2004)
 - Revocation of DEA Registration
 - Immediate Suspension of DEA Registration
 - 300,000 dosage units in three months
 - Phentermine, Phendimetrazine, Ambien

RX Network of South Florida, LLC

- 69 FR 62,093 (2004)
 - Revocation of DEA Registration
 - Immediate Suspension of DEA Registration
 - 19,300,000 dosage units of various controlled substances
 - Based on Internet Questionnaires
 - Not in the course of professional practice

Supreme Court Case

- United States v. Moore
 - 423 U.S. 122 (1975)
 - Usual course of professional practice
 - Patient with a Medical Complaint
 - History
 - Physical Examination
 - Nexus Between Complaint/History/Exam and Drug Prescribed

DEA Internet Policy

- 66 FR 21,181 (2001)
- Prescriptions can only be issued by a doctor acting in the usual course of professional practice
- Prescription not issued in the usual course of professional practice is not valid
- An Internet questionnaire alone is not sufficient to legally prescribe controlled substances

VERIFIED INTERNET PHARMACY PRACTICE SITES (VIPPS)

- National Association of Boards of Pharmacy
 - Licensed, legitimate, Inspection
 - 14 VIPPS Approved Pharmacies as of 06-27-2005
 - www.nabp.net/vipps/consumer/faq.asp

American Medical Association

- H-120.949 Guidance for Physicians on Internet Prescribing
 - valid patient-physician relationship, includes, but not limited to:
 - History and physical exam
 - Dialogue with patient
 - Follow up to assess outcome
 - Maintain medical record
 - Include electronic prescription in patient's medical record

Federation of State Medical Boards

- Created Model Guidelines for the Appropriate use of the Internet in Medical Purpose
 - Treatment and consultation made in an online setting will be held to same standard as face-to-face settings.
 - Treatment based solely on an online questionnaire is not acceptable

Suspicious Orders

- 21 CFR 1301.74
- Requires that registrants design and operate system to identify suspicious orders
- Report suspicious orders to DEA when discovered

Suspicious Orders

- Reporting a suspicious order to DEA does NOT relieve the distributor of the responsibility to maintain effective controls against diversion

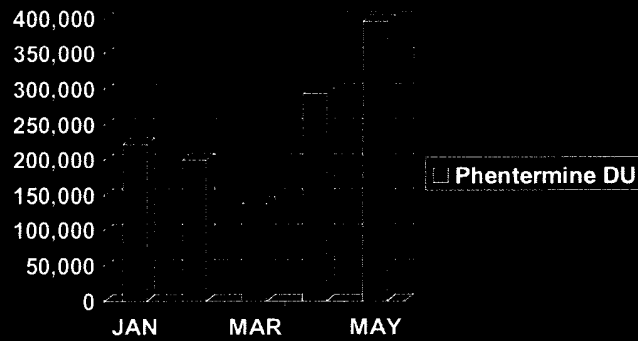
Suspicious Orders

- DEA cannot tell a distributor if an order is legitimate or not
- Distributor must determine which orders are suspicious and make a sales decision

Example #1

- Retail pharmacy
 - Quantities of drugs
 - Range of drugs sold
 - % controlled and % non-controlled
 - Size of orders over time
 - Location of store
 - Internet prices

Example #1



Example #2

- Retail Pharmacy
 - Location of store
 - Only Hydrocodone and Alprazolam
 - Very large quantities
 - FedEx boxes for delivery

INVESTIGATORS AT PHARMACY

Example #3

- Advised Distributor they are an Internet Pharmacy
- No VIPPS approval
- Frequent Large Orders
- Hydrocodone and Benzodiazepines
- 99% controlled substances
- No established business credit

AN INTERNET PHARMACY



Popular Internet Drugs

- Hydrocodone
- Phentermine
- Alprazolam

SUMMARY

- Prescriptions not written in the usual course of professional practice are not valid
- Drugs dispensed pursuant to invalid prescriptions are not for legitimate medical purpose, the drugs are diverted
- Not limited to Internet pharmacies

SUMMARY

- A pattern of drugs being distributed to pharmacies who are diverting controlled substances demonstrates the lack of effective controls against diversion by the distributor
- The DEA registration of the distributor could be revoked under public interest grounds

SUMMARY

- Any Distributor who is selling controlled substances that are being dispensed outside the course of professional practice must stop immediately
- DEA cannot guarantee that past failure to maintain effective controls against diversion will not result in action against a distributor

SUMMARY

- DEA will:
 - Meet with other distributors involved in distributing to Internet pharmacies
 - Provide this information to your employees at your request
 - Meet with Industry groups or associations to discuss issue if requested

Contact Information

Michael Mapes
Chief, E-Commerce Section

Kyle Wright
Chief, E-Commerce Operations Unit

INTERNET PHARMACY
Decision Questions

1. Have you physically inspected the pharmacy? _____
2. Does the pharmacy accept walk-in customers? _____
2. Is the pharmacy licensed for sales in all required states? _____
4. Does the pharmacy purchase a wide range of drug products from distributors? _____
5. What percentage of the pharmacy's drug purchases are controlled substances? _____
6. Has the pharmacy requested to pick up orders rather than have them delivered to the pharmacy? _____
7. Is the pharmacy ordering more than 3,000 dosage units of phentermine a month? _____
8. Is the pharmacy ordering more than 5,000 dosage units of hydrocodone combination products a month? _____
9. Is the pharmacy ordering more than 5,000 dosage units of alprazolam a month? _____

10. If the pharmacy has a web site or is related to a web site:

- a. Are reasonable retail prices listed on the web site? _____
- b. Is there a patient medical history questionnaire on the web site? _____
- c. Does the prescribing doctor perform a physical exam of each patient? _____
- d. Does the website accept third party payment (i.e. insurance) for the Internet prescriptions? _____
- e. Does the web site offer to sell drugs without a prescription? _____

11. Is the pharmacy VIPPS certified? _____

12. Who pays the distributor for the drugs, the pharmacy or a third party? _____

7-29-05